Title: DIVISION DESIGN CONTROL	Number: D65-04-01	Revision No.: OD	Effective Date: 31 JAN 97
	Prepared By: Thomas J. Underwood	Approved By: Thomas S. Dodson	Page: 1 OF 4

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STANDARD OPERATING PROCEDURE D65-04-01

From: D65
To: D65 Division

Subj: DIVISION DESIGN CONTROL

Ref:: (a) SOP D65-03-01, Division Tasking Reviews For Standards And Custom Products
(b) SOP D65-05-02, Division Document Control
(c) SOP D65-16-01, Division Quality Records

1. Purpose. To establish procedures and provide instructions for Design Control.

2. Scope and Application. This procedure applies to design and development of new products/services, improvement of existing products, and modification of products/services to satisfy special customer requirements or taskings. This procedure and instructions assign responsibilities for product design and design verification activities.

3. Policy. Establishing and maintaining design control is critical to both product configuration control and meeting sponsor/customer requirements. This procedure directly controls design and development activities of the Engineering, Production Control, Production, and Quality Assurance (QA) functions.

4. Procedure. The following procedures will be followed for receiving tasking and design inputs from a sponsor/customer, design planning, use of design aids/methods, holding design reviews, and control of design output.

a. Design Input - When new product/service development or improvement of existing product/service is initiated internally within the Division, the Branch/function and personnel who will perform the tasking(s) will receive a brief from the Division and/or ISEA program manager. The brief will describe the desired product/service in terms of its performance characteristics and design requirements, packaging design requirements (if applicable), and other relevant information pertinent to the product design. When design input is received externally, a design requirements review will be held with the sponsor/customer program manager and/or technical representative. Normally, the Engineering section responsible for the design will receive a design or design modification brief from the customer representative containing all sponsor/customer

and/or specification requirements. Design work will not begin until design requirements are mutually

agreed upon and understood and the design brief is approved by the Branch Head, the customer/tasking representative, the responsible engineering group/code, and QA prior to issue and release. Ambiguous or conflicting requirements will be resolved prior to design start.

b. Design Planning and Activity Assignments - The lead engineer or project engineer will be responsible for establishing a design plan prior to the start of any design activities. The plan, as a minimum, will divide the design process into phases, identify specific design requirements activities, assign responsibilities for performing each specific activity, and specify the design verification requirements. Design requirements will be traceable to a sponsor/customer task order, specification, design brief, or other similar formal documentation. The plan also schedules design and verification activities, including design reviews. For major designs , a program plan (POA&M) will be required if the cost is greater than or equal to $50K (See Standard Operating Procedure D65-01-05).

c. Organizational and Technical Interfaces - The lead engineer, project engineer, or program manager (in the case of large projects) will establish procedures for transmitting information and communication between the various groups involved in the design project. The design schedule will establish completion dates for release of critical information by each design group and/or activity. The lead engineer, project engineer, or program manager will have overall responsibility for coordinating the design groups.

d. Design Aids and Methods - The lead engineer or project engineer will determine which methods and criteria are used in the performance of calculations and other design activities. Only approved design aids and methods will be used in creating and/or modifying designs. Computer software used for performing calculations and other design support functions will be certified and approved. Standard software, purchased from commercial sources, will be ordered with certificates of testing and/or compliance whenever possible. If this documentation is not available, the software will require certification by QA. Software developed in-house will be tested and approved prior to release for use. Required documentation will include the testing specification approved by the lead engineer or project engineer and the testing record validating its performance. Software that has been used in design for at least one year prior to implementation of this procedure that has performed satisfactorily on previous design projects, may be approved by the lead engineer or project engineer without validation testing. Each new revision of software will be tested, approved, and identified with a configuration control/release number prior to use. Standards and other reference materials required for the design activities are available in the library. Unless otherwise specified, the latest standard issues and revisions will be used. Standards and reference materials that directly provide design input data are controlled in accordance with Standard Operating Procedure D65-05-02, Division Document Control.

e. Design Reviews - Design reviews will be conducted at predetermined design stages and will be scheduled in the design plan (or, in the case of large projects, a POA&M). As a minimum, two design reviews, a Preliminary Design Review and a Final Design Review, will be conducted. The Preliminary Design Review will be held early in the project. The purpose of this review is to evaluate and finalize the design input and reviewing conceptual solutions. The Final Design Review will occur after the design is substantially completed. The purpose of this review is to verify that design meets the specified requirements. Design reviews will be initiated by the lead engineer or project engineer but are conducted by the program managers (or other designated personnel). Attendees at the Design reviews will include program managers, project engineers, applicable technical group representatives from both the servicing organization and the sponsor/customer, and QA. The Design Reviews will specifically address such issues as primary and secondary design uses, environmental compatibility, reliability, serviceability, aesthetic characteristics, acceptance and rejection criteria, productability, capability to inspect and test, availability of qualified suppliers to provide specified materials and components, material handling and packaging, and life cycle support. Design Reviews for a major new product development project will be chaired by and approved by the Division Head and the responsible Branch Head. Formal design approval is required by both Division and sponsor/customer program and technical management before proceeding. Design reviews will formally documented and issued by the lead engineer or project engineer.

f. Primary and Secondary Design Output - Primary design output will consist of documents that define the product and instruct how to manufacture it. These documents will include drawings, specifications, procedures, workmanship standards, acceptance criteria, and other relevant documents. Secondary design output will consist of documents supporting the design. These documents include calculations, analysis, test results, verification and validation reports, and references to other documents supporting design development. All primary design output documents will be reviewed and approved prior to design release. Only the lead engineer, project engineer, or a formally designated representative has the authority to issue and release design documents. Design output documents will be controlled. Their establishment, review, authorization, issue, distribution and revisions will comply with Standard Operating Procedure D65-05-02, Division Document Control.

g. Design Verification and Validation - The purpose of design verification is to demonstrate that the design output meets the design input requirements. The purpose of design validation is to demonstrate that the designed product performs satisfactorily under real or simulated conditions of intended use. Design verification and validation activities will be identified in the design plan or program plan (for large and complex projects). Design verification and validation will be completed prior to the Final Design Review where the final design will be reviewed and

approved by Division and sponsor/customer program management, engineering, the responsible Branch

Head, and the Division Head. Design verification and validation may be accomplished "Based On Similarity" (BOS) if the design closely resembles an existing proven design. Verification and validation BOS will require sponsor/customer approval.

h. Design Changes - Design input changes may be requested during design projects by the sponsor/customer, production, or engineering. Design changes require approval from the sponsor/customer, the lead engineer or project engineer, production (if applicable), the responsible Branch Head, and the Division Head. After approval, the lead engineer or project engineer will incorporate the design change. The design or program plans will be adjusted (i.e. schedule) as required. Design changes to released products/services will be requested using the Engineering Change Request (ECR) form. After approval, an Engineering Change Notice will be issued as the formal authorization to make the design change. All design activities related to implementation of a design change will follow the same rules and controls that apply to initial designs as described in this procedure.

THOMAS S. DODSON